UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,598	04/27/2007	John E. O'Gara	59894US(49991)	3666

48990 7590 07/01/2010

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
LOEWE, ROBERT S	

ART UNIT	PAPER NUMBER
1796	

MAIL DATE	DELIVERY MODE
07/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,598	O'GARA, JOHN E.	
	Examiner	Art Unit	
	ROBERT LOEWE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,19-34,36,52 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,19-34,36,52 and 53* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments/remarks, filed on 6/22/10, have been fully considered but are not found to be persuasive. Regarding the 103(a) rejection of claims 1-16, 19-34, 36, 52 and 53 [O'Gara (US Pat. 6,528,167) in view of Holloway (US Pat. 6,210,570)], Applicants argue that O'Gara does not teach preparing hybrid **monolith** inorganic/organic materials, only hybrid inorganic/organic **particles**. The Examiner does not dispute this assertion. The Examiner relied on Holloway to explicitly teach the limitation of monolith material. Applicants argue that silica-based monoliths are most difficult to prepare and cite a review article by Guiochon to echo this assertion. Applicants further argue that Holloway does not explicitly prepare any inorganic/organic hybrid materials and does not provide any direction on how to obtain such monolithic materials. However, Holloway was relied upon to show that monolithic columns have many benefits over the more traditional columns based on discrete particles packed into a column bed. It is believed that Holloway provides ample motivation for a person having ordinary skill in the art to prepare monolithic silica-based columns. Applicants argue that there is no reasonable expectation on how a person having ordinary skill in the art could prepare such claimed materials given the disclosures of O'Gara and Holloway. However, a review article by Siouffi in 2003 (Journal of Chromatography A, 1000, 2003, 801-818) teaches that hybrid organic-inorganic based silica monolithic columns are known and teaches ways to prepare such monoliths. Further, Siouffi teaches at length the variables which go into preparing such sol-gel based monoliths, including the starting materials, sol-gel preparation and hydrolysis, additives, aging and drying (pages 803-808). It is submitted that at the time of the invention, a person having ordinary skill in the art, motivated by the desire to prepare hybrid organic-inorganic silica-based monolithic columns would have had ample knowledge at his or her disposal in which to carry out such an endeavor with only routine experimentation. Indeed, Rao et al. (Journal of Non-Crystalline Solids, 285, 2001, 202-209), which is an article cited by Siouffi explicitly teaches preparing monolithic hybrid inorganic-organic silica aerogels which are prepared from methyltrimethoxysilane and tetraethoxysilane. These two silane starting materials yield a hybrid inorganic-organic silica-based monolith. Therefore, Applicants argument that there would not be a reasonable expectation of success is not found to be persuasive.

The 103(a) rejection of claims 1-16, 19-34, 36, 52 and 52 [Walter (US 20030150811) in view of O'Gara (US Pat. 6,528,167)] has been withdrawn.

The obviousness double patenting rejection made in the previous Office action is wholly maintained.

Claim Objections

Claim 4 is objected to for the following informality: "he" should be corrected to --The--.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16, 19-34, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Gara (US Pat. 6,528,167) in view of Holloway (US Pat. 6,210,570).

Claims 1 and 52: O'Gara teaches and claims hybrid particles for chromatographic separations, wherein said particles have an interior and exterior surface, wherein the particles have the same claimed composition (claim 1). O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Holloway teaches porous silica monoliths for chromatographic separations (abstract). O'Gara and Holloway are combinable because they are from the same field of endeavor, namely, preparation of stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by O'Gara into the claimed porous monoliths and would have been motivated to do so since Holloway teaches that stationary phases which are comprised of a packed column of particles can cause reduction of flow rates which

necessitates higher column pressure (1:49-56). Holloway teaches that stationary phases comprising a continuous network (i.e., monolithic stationary phases) are alternatives which do not suffer from such drawbacks (1:57-59). A person having ordinary skill in the art understands from the teachings of Holloway that monolith formation is the result of gelation of the hydrosols taught therein. It is submitted that the amount of experimentation needed to prepare silica monoliths from the materials taught by O'Gara would not be undue given the disclosure of Holloway. Further, a person having ordinary skill in the art understands that when carrying out sol-gel reactions, advanced aging leads to the formation of networks of silica-based materials instead of discrete particles.

Instant claim 52 is a product-by-process claim. For such claims, patentability is based on the product itself, and not on its method of production. Therefore, it is submitted that Holloway provides motivation to prepare silica monoliths using the compositions as taught by O'Gara. A person having ordinary skill in the art would be cognizant of maintaining/preserving the attractive physical property limitations as taught by O'Gara, namely, the specific pore volumes, average pore diameters, specific surface areas and surface concentration of the R^6 groups. Therefore, a person having ordinary skill in the art would have found it obvious to prepare silica-based monoliths having the claimed physical properties as taught by O'Gara. As such, there would not be expected to be substantial differences in structure of the claimed silica monoliths as compared to the silica monoliths which is suggested by the combination of O'Gara in view of Holloway.

Since many of the remaining dependent claims of O'Gara are identical to those as claimed, a summary showing which claims read on the claims of O'Gara is shown below.

Claims 2-6 of O'Gara are identical or substantially identical to instant claims 2-6, respectively.

Claims 7-9: Claims 16-18 of O'Gara are identical to instant claims 7-9.

Claims 10-16: Claims 9-12 of O'Gara are identical or substantially identical to instant claims 9-15.

Claims 19-22: Claims 19-22 of O'Gara are identical or substantially identical to instant claims 19-22.

Claims 23-33: Claims 25-35 of O'Gara are identical or substantially identical to instant claims 23-29.

Claim 34: O'Gara teaches that the inorganic/organic hybrid particles have chromatographically-enhancing pore geometry (17:18-20).

Claim 53: O'Gara prepares hybrid particles having surface silicon-alkyl groups (example 1). O'Gara further teaches replacing one or more surface silicon-alkyl groups with fluoride, then with hydroxyl groups (Scheme on columns 15 and 16 and Example 6). O'Gara further teaches further modification of the surface methyl group converted hybrid inorganic/organic particles with a substituted siloxane group followed by end-capping with a trialkylhalosilane (example 9). O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Holloway teaches porous silica monoliths for chromatographic separations (abstract). O'Gara and Holloway are combinable because they are from the same field of endeavor, namely, preparation of stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by O'Gara into the claimed porous monoliths and would have been motivated to do so since Holloway teaches that stationary phases which are comprised of a packed column of particles can cause reduction of flow rates which necessitates higher column pressures (1:49-56). Holloway teaches that stationary phases comprising a continuous network (i.e., monolithic stationary phases) are alternatives which do not suffer from such drawbacks (1:57-59). A person having ordinary skill in the art understands from the teachings of Holloway that monolith formation is the result of gelation of the hydrosols taught therein. It is submitted that the amount of experimentation needed to prepare silica monoliths from the materials taught by O'Gara would not be undue given the disclosure of Holloway. Further, a person having ordinary skill in the art understands that when carrying out sol-gel reactions, advanced aging leads to the formation of networks of silica-based materials instead of discrete particles.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 13-17 and 50-55 of copending Application No. 11/631,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because formula (III) of claim 2 of the '341 Application is the same as formula I of instant claim 1 and reads on instant claims 1-3. The recited dependent claims of the '341 Application read on instant claims 4-15.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,250,214 in view of O'Gara (US Pat. 6,528,167).

Claim 1 of the '214 patent is substantially similar in scope for formulae II and III of instant claims 1 and 52. The key difference between the two claims is that the instant claims further have units of formula (IV), which are derived from the surface replacement of silicon-bonded alkyl groups with the silicon-bonded groups, R^4 as claimed. However, such a treatment step of the monoliths of claim 1of the '214 patent is believed to be obvious given the teachings of O'Gara. Specifically, O'Gara teaches that replacement of the surface silicon-methyl groups with

silanol groups result in hybrid particles with improved pH stability and improved chromatographic separation performance including peak tailing (2:20-24). With this knowledge, a person having ordinary skill in the art would have found it obvious to perform the same surface modifications of the hybrid silica particles as taught by O'Gara to the porous hybrid monolith materials as claimed in the '214 patent; the result being the instantly claimed porous inorganic/organic hybrid monolith material.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Relevant Art Cited

Additional prior art documents which are relevant to Applicants invention can be found on the attached PTO-892 form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT LOEWE whose telephone number is (571)270-3298. The examiner can normally be reached on Monday through Friday from 5:30 AM to 3:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L./
Examiner, Art Unit 1796
28-Jun-10

/RANDY GULAKOWSKI/
Supervisory Patent Examiner, Art Unit 1796